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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,807	08/21/2003	Craig A. Rosen	PS735	7993

22195 7590 05/31/2006

HUMAN GENOME SCIENCES INC.
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EXAMINER	
XIE, XIAOZHEN	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/644,807	ROSEN ET AL.	
	Examiner	Art Unit	
	Xiaozhen Xie	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-48* is/are pending in the application.

4a) Of the above claim(s) *48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Applicant's submission of Exhibits A. B. C, and amendment (remarks) on 17 March 2006 are acknowledged.

Claims 25-48 are pending. Claim 48 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 25-47 are under examination in this office action.

Claim Rejections Maintained

35 U.S.C. § 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The rejection of claims 25-47, under 35 U.S.C. § 101, as lacking either a specific, substantial, and credible asserted utility or a well established utility, is maintained for reasons of record in the previous office action (18 November 2005).

Applicant argues that the specification states that "polynucleotides and polypeptides corresponding to [gene 16 or HQAHD50], as well as antibodies against those polypeptides, may be useful for the diagnosis, prevention, and/or treatment of cancer and other hyperproliferative disorders", and therefore, the specification discloses a specific and substantial utility for the antibodies and polypeptides of the invention, since not all polypeptides or antibodies can be used to diagnose, prevent, and/or treat cancer and other hyperproliferative disorders. Applicant argues that this asserted utility is credible because the specific expression of the polypeptide of the invention in a broad

range of tumor-types and cancers. Applicant further provides post-filing date evidence in the form of reports by Vasmatzis et al. and by Olsson et al. that a prostate specific gene may be used to diagnose, prevent, or treat prostate cancer.

Applicants' argument has been fully considered but has not been found to be persuasive for reasons set forth in the previous Office Action (18 November 2005).

As was stated in the previous Office Action, no function or activity has been identified for the protein shown in SEQ ID NO: 213 encoded by HQAHD50. The specification discloses that the antibody that specifically binds to the polypeptide may act as an agonist or antagonist of the polypeptide of the instant invention, and may be used to target the polypeptide in both *in vitro* and *in vivo* diagnostic and therapeutic methods. Applicant lists a number of diseases, including cancer and immune system disorders, that may be diagnosed or treated by the instant invention, and provides post-filing date reports by Vasmatzis et al. and Olsson et al. that the instant antibody may be used to diagnose, prevent, or treat prostate cancer. However, the specification has provided no evidence that changes in levels or forms of the protein correlates with a diagnosis of a specific disease, and how to use the claimed invention for the treatment or diagnosis of any disease, particularly prostate cancer. There is no teaching as to what function or activity of the polypeptide is correlated with any diseases or conditions.

The report by Olsson et al. fails to support the asserted utility of the instant invention. Olsson et al. identified a PRAC2 gene, which shows 98.9% identity to the instant polypeptide of SEQ ID NO: 213. Olsson et al. investigated transcript levels of PRAC2 in 24 different tissues and in the prostate cancer cell lines LNCaP and PC3, and

found that the expression of PRAC2 is restricted to a few tissues and is predominantly in the prostate, rectum, and testis (pp. 126, left column, lines 1-4, and pp. 127, Fig. 2). While Olsson et al. stated that "both the detection and treatment of cancer would potentially benefit from the identification of new genes that are specifically expressed in prostate cancer", Olsson et al. do not teach that PRAC2 expression level in the prostate cancer cell lines is higher than the non-cancerous prostate tissues (pp. 127, Fig. 2). Olsson et al. stated that the chromosomal localization of the PRAC genes, 17q21, has been shown to undergo loss of heterozygosity (LOH) in prostate cancer, however, no such decrease in PRAC/PRAC2 expression could be found. Olsson et al. concluded that further studies are needed to understand the role of the PRAC genes in prostate cancer development, and that further investigations of the function of these genes should reveal what role they might play in prostate function (pp. 130, left column, last two paragraphs in Discussion section). Therefore, the role of PRAC2 in prostate cancer development had not been established, and little is known about the biological function or regulation of PRAC2 as late as 2003, and required further study at that time, while the instant application has a provisional filing date of February 23, 2001.

Further, the report by Vamatzis et al. also fails to support the asserted utility of the instant invention. Vamatzis et al. describe a procedure to discover genes that are specifically expressed in human prostate, and the genes identified could be useful in the targeted therapy of prostate cancer (pp. 300, Abstract). Vamatzis et al. teach that to obtain relatively specifically expressed clones, clusters that have hits to four or more different nonprostate organs are discarded (pp. 302, right column, lines 13 through pp.

303, left column, lines 1), and that any prostate ESTs that have zero hits in the non-prostate hit list are potentially from genes that are specifically expressed in prostate (pp. 303, right column, lines 13-15). The instant polypeptide, SEQ ID NO: 213, however, has been described as being expressed in a number of cancers such as prostate, pancreatic, breast, rectal, ovary, colon, kidney, lymphocyte, and so on. Therefore, the instant polypeptide is not within the scope of the "prostate specific" according to Vamatzis et al. The expression pattern of the instant polypeptide is also much broader in tissues than Olsson et al.'s finding even though the two proteins are nearly identical. Therefore, the teaching by Vamatzis et al. supports the rejection.

Clearly further research is required to identify the physiological significance and biological activity of this protein, and to identify its involvement in prostate cancer development. Without knowing the biological activity of this protein, and their correlation to any type of disease including prostate cancer, one skill in the art would not be able to use the antibodies to diagnose, prevent and/or treat any diseases or conditions. Therefore, the specification fails to provide an assertion of a specific and substantial utility. In the absence of knowledge of the physiological significance and biological activity of this protein, there is no immediately obvious patentable use for the antibody that bind to the protein. Since the instant specification does not disclose a "real world" use for the antibody that binds to the protein set forth in SEQ ID No: 213, then the claimed invention does not meet the requirements of 35 U.S.C. § 101 as being useful.

The rejection of claims 25-47 under 35 U.S.C. § 112, first paragraph, as being lack enablement since the claimed invention is not supported by either a credible,

specific and substantial asserted utility or a well established utility, is maintained for the reasons set forth above and in the previous office action (18 November 2005).

Conclusion

NO CLAIM IS ALLOWED.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Xiaozhen Xie whose telephone number is 571-272-5569. The examiner can normally be reached on M-F, 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol, Ph.D. can be reached 571-272-0835. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

Xiaozhen Xie, Ph.D.
May 9, 2006